



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/448,356	11/23/1999	DAVID CARL BURDICK	20257/110665	4950

7590

04/23/2003

MARK E WADDELL ESQ
BRYAN CAVE LLP
245 PARK AVENUE
NEW YORK, NY 101670034

EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 04/23/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/448,356

Applicant(s)

BURDICK ET AL.

Examiner

Sabiha Naim Qazi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 31 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-6 and 8-25 is/are pending in the application.
- 4a) Of the above claim(s) 9-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-6, 8, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 9-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

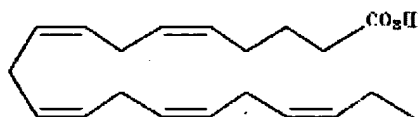
Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

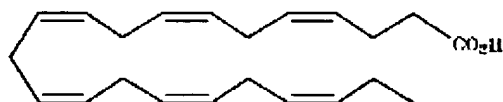
Art Unit: 1616

Acknowledgement is made of the response filed in paper no. 16, dated 1/31/03.

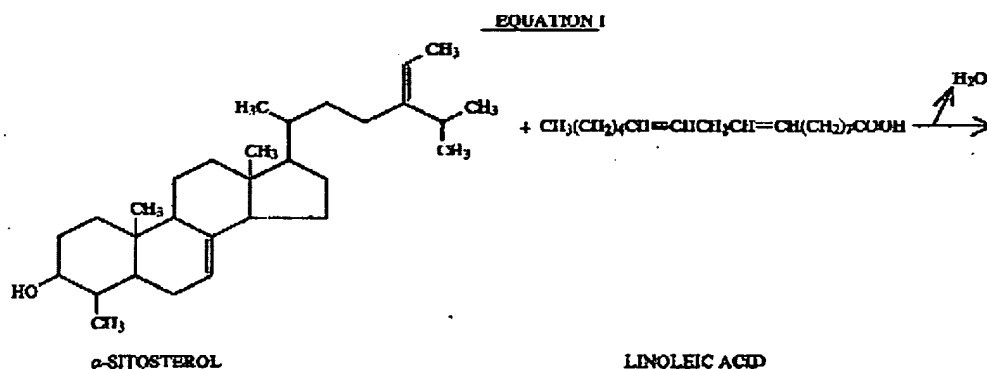
Claims 1-6, and 8-25 are pending. No claim is allowed. Arguments were fully considered but are found persuasive in part therefore, 102 (b) and 112 rejection is withdrawn and others are maintained for the same reasons as set forth in our previous action. For applicant convenience to understand the obviousness rejection structures of the EPA, DHA and a scheme showing the formation of unsaturated phytosterol esters are drawn.

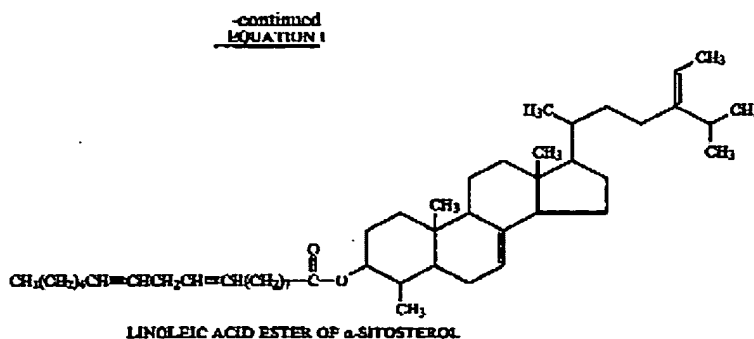


EPA



DHA





1. Claim 8 is rejected under 35 U.S.C. 103(a) as obvious over Mitchell (US Patent 4,588,717), Kamarei et al. (US Patent 4,879,312) and Miettinen et al. (WO 92/19640). See the entire documents especially lines 1-33, col. 7; col. 1-37, col. 8, equation 1 and examples in US '717; lines 39-59, col. 2 in US '312 and lines 22-30, page 9 and lines 20-24, page 10; lines 4-6, page 5; lines 8-37, page 6 in WO '640.

1. **Determining the scope and contents of the prior art.**

Prior art teaches a composition which embraces applicants claimed invention.

Mitchell teaches vitamin supplements containing phytosterol esters such as fatty acid esters of sterol, stigma sterol and taxasterol, in various combinations. Fatty acid have about 18-20 in addition to two carbon atoms of terminal carboxyl and methyl groups (lines 2-15, col. 6) and at least two double bonds such as arachidonic acid, linoleic acid and linolenic acids are used to make phytosterol esters, (see lines 21-58, col. 3; lines 43-65, col. 5; equation 1 and lines 1-11 in col. 8). Furthermore, it teaches that the reaction between any given phytosterol and any given fatty acid is essentially the same, and is characterized in equation 1 using sitosterol and linoleic acid as an exemplary fatty acid.

Miettinen et al. teaches a composition of b-sitostanol fatty acid ester mixture or fatty acid ester mixture. It teaches that physical properties of mixture can be modified easily by altering the fatty acid composition of the mixture. In addition to this, the fatty acid composition of the b-sitostanol fatty acid can also be selected so as to contain large amounts of monoenes and polyenes, whereby efficacy in lowering the cholesterol levels in serum are enhanced. See lines 22-30 on page 9. The reference also teaches fatty acid mixture containing 2-22 carbon atom and esterification of sitostanol.

Kamarei et al. teach that a diet rich in omega-3-fatty acids has beneficial effects in humans, including a reduction in plasma cholesterol and triglyceride levels, improved fat tolerance, prolonged bleeding time reduce platelet counts and decreased platelet adhesiveness. The omega-3-fatty acids are obtained mainly from dietary seafood. It teach n-3 Poly unsaturated fatty acids (PUFA) participation and reasons why these materials may be involved in alleviating ischemic heart diseases. Furthermore, it also teaches that one of n-3 PUFA i.e. eicosapentaenoic acid (EPA) and DHA reduces triglyceride and very low-density lipoprotein (VLDL) serum levels and reduces whole blood viscosity. (See lines 39-59, col. 2; lines 13-54, col. 3; Table 1 and 2 in col. 4).

2. Ascertaining the differences between the prior art and the claims at issue.

Instant claim 8 is drawn to a composition comprising:

Art Unit: 1616

- (a) a phytosterol compound produced from a reaction of phytosterol with eicosapentaenoic acid or docosahexaenoic acid and
- (b) a second ester compound which is the product of an esterification reaction between a phytosterol and/or phytostanol and
- (i) a fatty acid having less than 18 or more than 22 carbon atoms and at least three carbon-carbon double bonds and/or
- (ii) a fatty acid having 18-22 carbon atoms and less than three double bonds.

Presently claimed invention differ from the reference in claiming a composition containing combination of phytosterol ester compound produced by reaction of phytosterol and specific fatty acids eicosapentaenoic acid (EPA) (20-carbons) and or docosahexaenoic acid (DHA) (22-carbons), whereas prior art teaches compounds with fatty acids especially containing approximately 2-22 carbon atoms (lines 20-24, page 10). Instant claim is a selection of prior art teachings as EPA and DHA contain 20 and 22 carbons respectively which is taught by the prior art, see lines 20-25 on page 10 of WO '640 and US '717.

3. Resolving the level of ordinary skill in the pertinent art.

Therefore, it would be obvious to one skilled in the art at the time of invention to employ phytosterols composition in combination with omega-3-fatty acids and methods for lowering cholesterol and triglycerides in blood stream of a subject, because these agents are known individually for the treatment of the same disorders. See example 4 on page 11 of WO '640, where other oils such as sunflower, soybean olive and corn oil can also be used, which contain EPA and

DHA. All the ingredients of the instant invention are taught by the prior art for the same use.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The combination of agents, each of which is known for the same purpose, is considered *prima facie* obvious. At least additive therapeutic results would be expected. See *In re Kerkhoven* 205 U.S. P.Q. 1069.

Motivation is to prepare additional beneficial composition of sterols with unsaturated fatty acids such as omega-3-fatty acids, EPA, DHA, useful for lowering the cholesterol and triglyceride levels, because this use has been taught by the prior art for the said compositions. Preparation of supplemental vitamins, margarine and mayonnaise is taught by the prior art cited above.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

2. Claim(s) 1-6, 24 and 25 are rejected under 35 U.S.C. 103 as being unpatentable over combined teachings of Miettinen et al. (WO 92/19640) and Mitchell (US 4,588,717). Mitchell (US Patent 4,588,717) teaches vitamin supplements containing phytosterol esters such as fatty acid esters of sterol, stigmasterol and taxasterol, in various combinations, a composition of the phytosterols, such as sitosterol, stigmasterol, taraxasterol etc reacted with linoleic

Art Unit: 1616

acid, (18-carbons, two double bonds), linolenic acid (18-carbons, 3-double bonds), arachidonic acid (20-carbons, two double bonds). Fatty acid have about 18-20 in addition to two carbon atoms of terminal carboxyl and methyl groups (lines 2-15, col. 6) and at least two double bonds such as arachidonic acid, linoleic acid and linolenic acids are used to make phytosterol esters, (see lines 21-58, col. 3; lines 43-65, col. 5; equation 1 and lines 1-11 in col. 8). Furthermore, it teaches that the reaction between any given phytosterol and any given fatty acid is essentially the same, and is characterized in equation 1 using sitosterol and linoleic acid as an exemplary fatty acid.

Miettenen et al. teaches a composition of b-sitostanol fatty acid ester mixture or fatty acid ester mixture. It teaches that physical properties of mixture can modified easily by altering the fatty acid composition of the mixture. In addition to this, the fatty acid composition of the b-sitostanol fatty acid can also be selected so as to contain large amounts of monoenes and polyenes, whereby efficacy in lowering the cholesterol levels in serum are enhanced. See lines 22-30 on page 9. The reference also teaches fatty acid mixture containing 2-22 carbon atom and esterification of sitostanol which is instantly claimed. See the entire documents especially lines 22-30, page 9 and lines 20-24, page 10; lines 4-6, page 5; lines 8-37; page 6 in WO '640.

Instant claims differ from the reference in claiming reaction of phytosterol with specific fatty acids i.e. docosaheptaenoic acid and eicosaheptaenoic acid where as

Art Unit: 1616

prior art teaches reaction product of phytosterol with fatty acids especially containing approximately 2-22 carbon atoms. Instant claims are a selection of prior art teachings.

It would have been obvious to one skilled in the art to prepare additional beneficial composition by selecting any fatty acids for example, docosahexaenoic acid and eicosahexaenoic acid from fatty acid 2-22 carbon atoms taught by the prior art. There has been ample motivation provided by the prior art to prepare the instant invention. Instant compositions would have been obvious at the time of invention. The subject as instantly claimed would have been obvious to one at the time of invention.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

Art Unit: 1616

the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


SABIHA QAZI, PH.D
PRIMARY EXAMINER

April 21, 2003